UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

IN RE:	:	MDL DOCKET NO. 1724
VIAGRA PRODUCTS LIABILITY LITIGATION	:	Judge Paul A. Magnuson
This Document Relates To: **All Cases**	:	

EXPERT REPORT OF JOHN J. MULCAHY, M.D.

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EXPERT REPORT OF JOHN J. MULCAHY, M.D.

Qualifications

1. I am a board certified urologist and fellow of the American College of Surgeons. I have focused much of my practice on the study and treatment of erectile dysfunction ("ED"). I was the Chief of Urology at Wishard Memorial Hospital in Indianapolis, Indiana, from 1978 to 1998, and a professor of Urology at the Indiana University School of Medicine until 2006. In addition to numerous academic honors and awards in the field of urology, my credits include an M.S. in Urology, a Ph.D. in Physiology, and more than 35 years' experience treating men with ED. I am currently a clinical professor of Urology at the University of Arizona.

2. I have served as the principal investigator in more than 35 grant-funded studies on various topics within the field of urology, ten of which were clinical trials involving pharmaceutical products under investigation for the treatment of ED.

3. I have published more than 60 peer reviewed articles and four authoritative medical texts on the subject of sexual dysfunction and its treatment. I serve as a reviewer for *Urology*, *Journal of Urology*, the *Journal of Sexual Medicine* and the *International Journal of Impotence Research*, the principal publications for physicians who specialize in this field of medicine. I also sit on the editorial boards of the *International Journal of Impotence Research* and *Urology Times*. I am a past President of the Sexual Medicine Society of North America (formerly known as the Society for the Study of Impotence).

4. My expert qualifications and publications are set forth more fully in my *curriculum vitae*, which is attached as Exhibit A.

5. I am being compensated in this case at the rate of $400 per hour for consultation and $500 per hour for testimony at deposition or trial.

6. I have testified, at deposition or trial, as an expert witness over the past four years on the cases listed in Exhibit B.

Materials Reviewed And Relied Upon In Forming Opinions

7. In forming my opinions, I have reviewed the medical and scientific literature regarding Viagra®, including, but not limited to, the articles specifically referenced in this report, the Overall Summary of Safety and Summary of Efficacy of the Viagra® New Drug Application ("NDA"), and the FDA's Joint Clinical Review of the New Drug Application. In addition, I have reviewed the expert reports of Dr. Michael Witt and Dr. Stephen E. Kimmel.

8. In addition to the materials referenced in paragraph 7, I am relying on medical literature concerning ED and its treatment, and other literature referenced in this report. I am also relying on my knowledge and experience as a practicing clinical urologist, a professor of medicine, a clinical researcher, a scholar, and a practitioner who has prescribed Viagra® to

patients for whom Viagra® is indicated. All of the opinions which I am rendering are generally accepted in the medical community and based on methodology which is generally accepted as reliable in the medical community. Where appropriate, reference literature is cited in this disclosure statement. These references are illustrative and not exhaustive.

Substance Of Facts And Opinions And Summary Of Grounds For Opinions

9. I will testify to the following opinions to a reasonable degree of medical certainty:

a. ED is a serious disorder affecting many millions of men. Erectile dysfunction can cause severe emotional damage to patients and their partners. Treatment of erectile dysfunction is important in helping patients and their partners maintain their health, well-being and quality of life.

b. Viagra® is an effective, reliable and well-tolerated treatment for ED. Treatment with Viagra® substantially improves erectile function and is effective in men whose ED results from a variety of causes. In this regard, Viagra® substantially improves the rate of successful attempts at sexual intercourse.

c. Viagra® was the first available oral treatment for ED and was a major medical advance, offering significant advantages in the treatment of ED over prior treatment options. For most men afflicted with ED, Viagra® is now the first treatment option because it is reliable, has a substantial track record of safety and efficacy, has minimal side effects, is simple to use, is

non-invasive, and enables the patient to achieve an erection in response to sexual stimulation.

d. Viagra® is improving the quality of the lives of patients and their partners. Patient satisfaction with Viagra® has been high.

e. Viagra is, and has been, appropriately labeled with regards to reported cases of NAION.

ED Is A Serious Disorder Affecting Many Millions Of Men

10. ED is the persistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance.[1] ED is a serious disorder which is estimated to afflict as many as 30 million men in the United States.[2] In a leading epidemiologic survey, the Massachusetts Male Aging Study ("MMAS"), one third of 1,290 men aged 40 to 70 reported having moderate or complete ED.[3] The prevalence of ED was shown to increase by approximately 10% with each decade of life, from 39% of men 40 years of age with minimal, moderate or complete ED to 67% of such ED in men 70 years of age.[4] Although associated with aging, ED is not a direct

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1 National Institutes of Health Consensus Development Panel on Impotence, *Impotence*, 270 JAMA 83-90, at 83 (Jul. 1993) [hereafter "NIH Consensus"].

2 *Id.* at 84; *see also* Goldstein, I., et al., *Oral Sildenafil in the Treatment of Erectile Dysfunction*, 338 New Eng. J. Med. 1397-1404, at 1397 (May 1998) [hereafter "New England Journal of Medicine"]; Process of Care Consensus Panel, *Position Paper: The Process of Care Model for Evaluation and Treatment of Erectile Dysfunction*, 11 Int'l J. Impotence Research 59-74, at 68 (1999) [hereafter "Consensus Panel"].

3 Feldman, H.A., et al., *Impotence and Its Medical and Psychosocial Correlates: Results of the Massachusetts Male Aging Study*, 151 J. Urology 54-61, at 55 (Jan. 1994).

4 *Id.*

consequence of the aging process, but rather a result of other age-related conditions and some medications taken to treat them.[5]

11. ED has different causes which can be biological (organic), psychological, or both. Although biological causes play a role in most cases of ED, psychological factors such as self-confidence, anxiety, and partner communication and/or conflict are often important contributing causes.[6]

12. ED occurs when there is disruption of the complex sequence of interrelated psychological, neurological and vascular events resulting in an erection. In a normal, adult male, sexual stimulation leads to the release of a chemical substance called nitric oxide in two tubular structures in the penis called corpora cavernosa. Nitric oxide then induces the formation of a chemical called cGMP. cGMP, in turn, reduces intracellular calcium, which causes the smooth muscle cells of the penile arteries and trabecular tissue to relax, thereby permitting blood to flow into the penis and blood entrapment within the penis, resulting in an erection.[7]

13. This complex sequence of events may be disrupted in different ways. A psychological impairment, a nervous disorder, a vascular problem or other biological event that interferes with the production of nitric oxide may lead to an inadequate supply of cGMP, resulting in insufficient blood flow to cause an erection. Such a disruption may result from any of the following conditions:

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5 Padma-Nathan, H., et al., *Efficacy and Safety of Oral Sildenafil in the Treatment of Erectile Dysfunction: A Double-Blind, Placebo-Controlled Study of 329 Patients*, 52 Int'l J. Clinical Practice 1 (1998) [hereafter "Efficacy and Safety"].

6 NIH Consensus, *supra*, at 84; *see also* Consensus Panel, *supra*, at 60 (listing depression and anger among the psychological correlates of ED).

7 Andersson, K., *Physiology of Penile Erection*, 75(1) Physiological Reviews 191-236 (Jan. 1995); New England Journal of Medicine, *supra*, at 1397.

a. *Chronic Illnesses* -- Chronic illnesses that impede blood flow to the penis or smooth muscle cell relaxation in the penis, such as atherosclerosis, diabetes, and hypertension can result in ED.[8] Atherosclerotic disease is associated with approximately 40 % of the cases of ED in men over the age of 50.[9] ED also occurs in 28-59% of men with diabetes of any type, depending on patient age and the severity of diabetes.[10] Other chronic illnesses which can lead to ED include renal or kidney failure,[11] hepatic or liver failure,[12] multiple sclerosis,[13] Alzheimer's disease[14] and chronic obstructive pulmonary disease.[15]

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8 Efficacy and Safety, *supra*, at 1; Consensus Panel, *supra*, at 59-60.

9 Efficacy and Safety, *supra*, at 1 (citing Kaiser, F.E., et al., *Impotence and Aging: Clinical and Hormonal Factors*, 36 J. Am. Geriatric Soc. 511-19 (1988)).

10 Efficacy and Safety, *supra*, at 1 (citing Rubin, A., et al., *Impotence In Diabetes Mellitus*, 168 JAMA 498-500 (1958)); *see* Kolodny, R.C., et al., *Sexual Dysfunction In Diabetic Men*, 23 Diabetes 306-09 (1974); McCulloch, D.K., et al., *The Prevalence of Diabetic Impotence*, 18 Diabetologia 279-83 (1980); Rundles, R.W., *Diabetic Neuropathy*, 24 Medicine 111-60 (1945).

11 Efficacy and Safety, *supra*, at 1 (citing Abram, H.S., et al., *Sexual Functioning In Patients With Chronic Renal Failure*, 160 J. Nervous Mental Dis. 220-26 (1975)).

12 Efficacy and Safety, *supra*, at 1 (citing Cornely, C.M., et al., *Chronic Advanced Liver Disease and Impotence; Cause and Effect*, 4 Hepatology 1227-30 (1984)).

13 Efficacy and Safety, *supra*, at 1 (citing Goldstein, I., et al., *Neurological Abnormalities In Multiple Sclerosis*, 128 J. Urology 541-45 (1982)).

14 Efficacy and Safety, *supra*, at 1 (citing Zeiss, A.M., et al., *The Incidence and Correlates of Erectile Problems In Patients With Alzheimer's Disease*, 19 Arch. Sex. Behav. 325-31 (1990)).

15 Efficacy and Safety, *supra*, at 1 (citing Fletcher, E.C. & Martin, R.J., *Sexual Dysfunction and Erectile Impotence In Chronic Obstructive Pulmonary Disease*, 81 Chest 413-21 (1982)).

b. *Medications* -- Certain life-saving medications, such as drugs that are used to treat high blood pressure, can cause ED.[16] For such patients, the side- effect of ED resulting from these medications may cause them to fail to take the medication as directed, thereby placing them in grave danger unless there is some other way to relieve that side-effect, such as Viagra®. In addition to drugs used to treat high blood pressure, certain drugs used to treat depression (anti-depressants), irregular heart beat (anti-arrhythmics), prostate cancer (anti-androgens) and ulcers (H_2 blockers), also are commonly associated with ED.[17]

c. *Injuries* -- Some types of severe injuries to the nervous system, such as spinal cord injuries, can cause ED.[18] In such cases, the man's injury can prevent the nerve impulses which stem from sexual arousal from producing sufficient nitric oxide to trigger adequate blood flow to his penis. The lack of blood flow, in turn, disables him from achieving an erection.

d. Some *surgical procedures*, such as prostate cancer surgery, can cause ED as a result of trauma to the vascular system in the area of the penis.[19]

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16 Finger, W.W., et al., *Medications That May Contribute to Sexual Disorders*, 44 J. Family Practice 33-43, at 34 (Jan. 1997); Segraves, R.T. & Segraves, K.B., *Aging and Drug Effects on Male Sexuality, in* Erectile Disorders: Assessment and Treatment, 96 (Rosen, R.C. & Leiblum, S.R., eds., 1992); Grimm, R.H., *Long-term Effects on Sexual Function of Five Antihypertensive Drugs and Nutritional Hygienic Treatment in Hypertensive Men and Women,* 29 Hypertension 8-14 (Jan. 1997); NIH Consensus, *supra*, at 83.

17 Consensus Panel, *supra*, at 64.

18 Padma-Nathan, H. & Kanellos, A., *The Management of Erectile Dysfunction Following Spinal Cord Injury,* 10(2) Seminars in Urology 133-37 (May 1992); Consensus Panel, *supra*, at 60.

19 Montorsi, F., et al., *Recovery of Spontaneous Erectile Function After Nerve-Sparing Radical Retropubic Prostatectomy with or without Early Intracavernous Injections of*

(continued...)

e. *Psychological problems* -- ED can also result from psychological problems such as depression and anxiety.[17] ED often results from a combination of psychological and biological conditions.

14. The impact of undiagnosed or untreated ED is often profound and far-reaching. In addition to undermining sexual performance, ED may lead to depression, anxiety, diminished self-esteem, a poor-self image and disruption of intimate relationships.[18] As the NIH Consensus Statement observes:

> In men of all ages, erectile failure may diminish willingness to initiate sexual relationships because of fear of inadequate sexual performance or rejection. Because men, especially older men, are particularly sensitive to the social support of intimate relationships, withdrawal from these relationships because of such fears may have a negative effect on their overall health.[19]

Alprostadil: Results of a Prospective, Randomized Trial, 158(4) J. Urology 1408-10 (Oct. 1997); Consensus Panel, *supra*, at 60.

17 NIH Consensus, *supra*, at 84; Shabsigh, R., et al., *Increased Incidence of Depressive Symptoms in Men with Erectile Dysfunction,* 52(5) Urology 848-52, at 851 (1998); Menza, M., et al., *Effect of Sildenafil Citrate in Men With Erectile Dysfunction and Depression* (poster presented on May 19, 1999 at the 152nd Annual Meeting of the American Psychiatric Association); Rosen, R., et al., *The Efficacy and Safety of Sildenafil Citrate for the Treatment of Erectile Dysfunction in Men With Comorbid Depression* (poster presented on May 19, 1999 at the 152nd Annual Meeting of the American Psychiatric Association).

18 Efficacy and Safety, supra, at 4; see also NIH Consensus, supra, at 84; Consensus Panel, supra, at 68 ("Despite increased public awareness of [sexual dysfunction], there are few aspects of human behavior that have as much of a capacity to affect our self-esteem and overall sense of well-being."); *see also* Montorsi, F. et al., *Erectile function function and assessments of erection hardness correlate positively with measures of emotional well-being, sexual satisfaction, and treatment satisfaction in men with erectile dysfunction treated with sildenafil citrate (Viagra)*, Urology, 2006, 68(3 Suppl):26-37; Kadioglu, A. et al., *Quality of erections in men treated with flexible-dose sildenafil for erectile dysfunction: multicenter trial with a double-blind, randomized, placebo-controlled phase and an open-label phase*, Journal of Sexual Medicine, 2008, 5(3):726-734.

19 NIH Consensus, *supra*, at 84.

15. Numerous published medical articles have recognized the long-term health benefits associated with sexual activity. Moreover, studies have shown that treating men with ED has improved sexual function in their female partners.[20]

Viagra® Is An Effective, Reliable And Well-Tolerated Treatment For ED

16. Viagra® is an oral medication for the treatment of erectile dysfunction which was approved by the FDA in March 1998.[21] Viagra® works by selectively and specifically inhibiting the activity of phosphodiesterase type 5, or PDE 5.[22] Inhibition of PDE 5 results in decreased breakdown of cGMP, thereby permitting increased and/or sustained blood flow to the penile tissue.[23]

17. Viagra® has been proven effective in patients who have ED as a result of biological, psychological and mixed causes. In the clinical trials on which Pfizer relied to establish efficacy in seeking FDA approval of the Viagra® New Drug Application, and on which the FDA relied in approving that application, the proportion of patients who reported improved erections was significantly higher for those receiving Viagra® than among those who received a

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20 Cayan, S., et al., *The Assessment of Sexual Functions in Women with Male Partners Complaining of Erectile Dysfunction: Does Treatment of Male Sexual Dysfunction Improve Female Partner's Sexual Functions?*, J. of Sex and Marital Ther., 2004, 30:333-341.

21 Letter from Robert Temple, Director, Office of Drug Evaluation I, FDA, to Sandra Croak-Brossman, Pfizer Central Research (Mar. 27, 1998).

22 Kloner, R.A. & Jarow, J.P., *Erectile Dysfunction and Sildenafil Citrate and Cardiologists*, 83 Am. J. Cardiology 576-82, at 578 (Feb.1999); Zusman, R.M., et al., *Overall Cardiovascular Profile of Sildenafil Citrate,* 83(5) Am. J. Cardiology 35C-44C (Mar. 1999); Wallis, R.M., et al., *Tissue Distribution of Phosphodieterase Families and the Effects of Sildenafil on Tissue Cyclic Nucleotides, Platelet Function, and the Contractile Responses of Trabeculae Carneae and Aortic Rings in Vitro*, 83(5) Am. J. Cardiology 3C-12C (Mar. 1999).

23 *Id.*

placebo.[24] Overall, Viagra® was administered to over 3,700 patients in the clinical trials.[25] In 18 double-blind placebo-controlled studies, a total of 4,274 patients with ED between the ages of 18 and 87 were evaluated (2,722 sildenafil, 1,552 placebo).[26]

18. For example, in a double-blind, placebo-controlled, fixed-dose study of 532 patients with ED, men who received sildenafil reported higher scores on questions designed to measure the frequency of sexual penetration and the maintenance of erections after penetration.[27] For example, men given doses of 25, 50 and 100 mg of sildenafil reported increases from baseline in the mean score assessing frequency of penetration that were 60, 84 and 100% higher, respectively, compared with a 5% increase for men receiving placebo.[28] Similarly, men receiving doses of 25, 50 and 100 mg of sildenafil reported increases from baseline on scores assessing the maintenance of erections that were 121, 133 and 130% higher, compared with 24% for those receiving a placebo.[29]

19. In another study of 329 patients treated with a placebo or Viagra® for 12 weeks, 74% of the patients who received Viagra® reported improved erections as compared with

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24 FDA Joint Clinical Review § 7.3, *Summary of Key Effectiveness Findings*; *see generally* Morales, A., et al., *Clinical Safety of Oral Sildenifil Citrate (Viagra™) in the Treatment of Erectile Dysfunction*, 10 Int'l J. Impotence Research 69-74, at 70 (1998); New England Journal of Medicine, *supra*.

25 Morales, A., et al., *supra*, at 70.

26 *Id.*

27 New England Journal of Medicine, *supra*, at 1399.

28 *Id.*

29 *Id.*

only 16% of those who received a placebo.[30] 69% of patients treated with Viagra® reported erections sufficient for vaginal penetration on most or all occasions compared with 23% of patients treated with a placebo.[31] 62% of patients receiving Viagra® indicated that they maintained their erections after penetration on most or all occasions, compared with 16% of patients receiving a placebo.[32] Overall, 59% of patients treated with Viagra® reported that they were able to achieve and maintain their erections on most or all occasions, as compared with 15% of the placebo-treated patients.[33] These results are consistent with the results of the other clinical trials used to establish the efficacy of Viagra®.[34]

20. The efficacy of Viagra in the treatment of erectile dysfunction has been demonstrated in numerous studies since its introduction in the market. In a recent study, investigators evaluated efficacy, tolerability, and treatment satisfaction after initiating treatment

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30 Efficacy and Safety, *supra*, at 1.

31 *Id.* at 3.

32 *Id.*

33 *Id.*

34 Pfizer Final Study Report: Protocol 148-102, *A Double-Blind, Randomised, Placebo Controlled, Parallel Group, Fixed-Dose, Multicentre Study to Assess the Efficacy and Safety of Sildenafil (UK-92,480) Administered Over Six Months to Male Patients with Erectile Dysfunction* (Jul. 17, 1997); Pfizer Final Study Report: Protocol 148-103, *A Double-Blind Randomised, Placebo Controlled, Parallel Group, Multicentre, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil Administered as Required to Male Patients with Erectile Dysfunction* (Jul. 17, 1997); Pfizer Final Study Report: Protocol 148-363, *A Double-Blind, Randomised, Placebo Controlled, Parallel Group, Multicentre, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil (UK-92,480) Administered Over Six Months to Male Patients with Erectile Dysfunction* (Jun. 30, 1997); Pfizer Final Study Report: Protocol 148-364, *A Double-Blind, Randomised, Placebo-Controlled, Parallel Group, Multi-Centre Study to Assess the Efficacy and Safety of Fixed Doses of Sildenafil Administered for Three Months to Male Patients with Erectile Dysfunction* (Jun. 26, 1997).

with sildenafil 50 mg and later titrating to 100 mg, compared with continuing treatment with sildenafil 50 mg, in men with erectile dysfunction. Their finding showed that after initial treatment with sildenafil 50 mg, patients titrated to 100 mg experienced further increases in efficacy and satisfaction. [35]

21. In another recent placebo-controlled, double-blind study, men with erectile dysfunction treated with sildenafil reported improved erections four times as often as those in the placebo-treated group, and improved emotional and overall satisfaction. [36]

22. A double-blind, placebo-controlled study conducted in Mexico demonstrated the efficacy of sildenafil in 95 men with clinically diagnosed erectile dysfunction who were in a stable relationship, as compared with a placebo treatment group. Sildenafil treatment led to significant improvements in self-esteem, confidence and relationship satisfaction. These data support an earlier study showing that Latin American men taking sildenafil have similar safety and efficacy profiles compared to non-Latin counterparts.[37] Effective ED treatment with sildenafil in a double-blind, placebo-controlled clinical trial conducted in Brazil, Mexico,

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35 Buvat, J. et al., Efficacy, tolerability and satisfaction with sildenafil citrate 100-mg titration compared with continued 50-mg dose treatment in men with erectile dysfunction, *British Journal of Urology International*, August 2008.

36 Jones, L. et al., Effect of sildenafil citrate on the male sexual experience assessed with the Sexual Experience Questionnaire: a multicenter, double-blind, placebo-controlled trial with open-label extension, *Journal of Sexual Medicine*, August 2008, 8:1955-64.

37 Zonana-Farca, E. et al, Self-esteem, confidence and relationship satisfaction in men with erectile dysfunction: a randomized, parallel-group, double-blind, placebo-controlled study of sildenafil in Mexico, *International Journal of Impotence Research, July-August* 2008, 4:402-8.

Australia and Japan also showed pooled cross-cultural improvements in self-esteem, confidence and relationship satisfaction.[38]

Viagra is Effective for Specific ED Patient Populations

23. Sildenafil is effective in several specific patient populations that are effected by erectile dysfunction, including the difficult-to-treat subpopulations such as diabetes mellitus and spinal cord injuries. In a study conducted in men with erectile dysfunction and spinal cord injuries, 90% of patients reported improvement in erection quality after sildenafil.[39]

24. In a flexible-dose escalation study, 219 men with Type 2 diabetes showed significant improvement with sildenafil in all efficacy variables (hardness, penetration and overall satisfaction) compared with men treated with placebo. Efficacy was similar irrespective of the level of glycemic control or number of diabetic complication. Sixty-five percent of patient reported improvement in their erections compared with 11% of those receiving placebo. None of the patients experienced any adverse reactions on blood glucose levels during treatment with sildenafil.[40]

25. Men who have undergone treatment for prostate cancer have also greatly benefited from treatment with sildenafil. Erectile dysfunction is the most common side effect of all prostate cancer treatments and it is not unusual for men to delay treatment or to choose less effective treatment that are associated with a shorter life expectancy because of their concerns

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38 Althof, E. et al., Sildenafil citrate improves self-esteem, confidence, and relationships in men with erectile dysfunction: Results from an international, multi-center, double-blind, placebo-controlled trial, *Journal of Sexual Medicine*, 2006, 3(3):5210529.

39 Moemen, M. et al., Erectile dysfunction in spinal cord-injured men: different treatment options, *International Journal of Impotence Research*, March-April 2008, 20(2):181-187.

40 Basu, A and Ryder, R., New Treatment Options for Erectile Dysfunction in Patients with Diabetes Mellitus, *Drugs*, 2004, 23:2667-2688.

about treatment-related erectile dysfunction and urinary incontinence. The availability of sildenafil for this population has allowed men to make earlier and better treatment decisions.[41], [42]

26. Researchers followed a sample of 1,288 men with localized prostate cancer who underwent radical prostatectomy at two and five year intervals. Various quality of life data were collected, including use of erectile aids. Sildenafil was the most commonly used therapy (43% ever used) and 45% of users reported that it helped their erectile dysfunction "somewhat" or "a lot."[43]

27. In a study of men treated with bilateral nerve-sparing radical retropubic prostatectomy, men with normal erectile function before surgery were randomized to double-blind sildenafil (50 or 100 mg) or placebo nightly for 36 weeks, followed by an 8-week drug-free period before assessment of erectile function. Spontaneous erectile (i.e., were erections good enough for satisfactory sexual activity?) occurred in only 4% of the placebo group versus 27% of the sildenafil group, demonstrating that nightly sildenafil administration for 36 weeks after surgery markedly increased the return of normal spontaneous erections. There was also notable improvement in lower urinary tract symptoms.[44]

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41 Penson, D., The effect of Erectile Dysfunction on Quality of Life Following Treatment for Localized Prostate Cancer, Reviews in Urology, 2001, 3(3):113-119.

42 Zeliadt, S., et al., Why Do Men Choose One Treatment Over Another? A Review of Patient Decision Making for Localized Prostate Cancer, Cancer, 2006.

43 Penson, D. et al., 5 -year urinary and sexual outcomes after radical prostatectomy: results from the Prostate Cancer Outcomes Study, *Journal of Urology*, May 2008, 179(5 Suppl):S40-4

44 Padma-Nathan, H. et al., Randomized, double-blind, placebo-controlled study of postoperative nightly sildenafil citrate for the prevention of erectile dysfunction after bilateral nerve-sparing radical prostatectomy, *International Journal of Impotence Research*, 2008 Sep-Oct;20(5):479-86.

Viagra Has Additional Health Benefits

28. Sildenafil has also been shown to have additional health benefits beyond the restoration of erectile function. A study conducted with men suffering from both erectile dysfunction and benign prostatic hypertrophy showed improvement in erectile quality and function, and urinary symptoms associated with an enlarged prostate.[45]

29. Female partners of men with erectile dysfunction also benefit from the treatment of erectile dysfunction with sildenafil. In a study designed to compare sexual functioning between women with male partners who have erectile dysfunction and women without partners with erectile dysfunction, researchers were able to show that sexual function is affected by male erection status and is improved after the treatment of male sexual dysfunction.[46]

30. Other recent studies have similarly demonstrated that nightly Viagra administration following nerve-sparing prostatectomy (which frequently results in ED) increases the return of normal spontaneous erections.[47] The authors in fact noted that it has become "common practice" to provide Viagra post-operatively to men undergoing nerve-sparing prostatectomy.

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45 McVary, K. et al., Sildenafil citrate improves erectile function and urinary symptoms in men with erectile dysfunction and lower urinary tract symptoms associated with benign prostatic hyperplasia: a randomized, double-blind trial, *Journal of Urology*, 2007, 177:1071-1077.

46 Cayan, S. et al., The assessment of sexual functions in women with male partners complaining of erectile dysfunction: does treatment of male sexual dysfunction improve female partner's sexual functions?, Journal of Sex and Marital Therapy, 2004, 30:333-341.

47 Padma-Nathan, H., et al., Randomized, double-blind, placebo-controlled study of postoperative nightly sildanefil citrate for prevention of erectile dysfunction after bilateral nerve-sparing prostatectomy, *International Journal of Impotence Research*, 2002, 20:479-486.

Viagra® Is A Major Medical Advance, Offering Significant Advantages In The Treatment Of ED Over Alternative Treatment Options; For Most Men Afflicted With ED, Viagra® Is Now The First Treatment Option To Be Considered

31. Viagra® is a major medical advance in the treatment of ED. Before its introduction, men suffering from ED had only a few treatment options, each of which had significant drawbacks. They included:

a. *Oral drug therapy*, including yohimbine alone or in combination with trazodone, neither of which have been approved by the FDA as a safe and effective oral treatment for ED. The published literature regarding these drugs notes the absence of data supporting efficacy and also reports low patient satisfaction.[48]

b. *Injection therapy* using papaverine, phentolomine or prostaglandin E-1 (alprostadil) which a patient must inject in the corpora cavernosa of his penis some period of time before engaging in sexual intercourse. Published reports indicate moderate patient satisfaction because of pain, fear of injection, and difficulty and awkwardness of performing injections in the course of intimate activities as well as a high drop-out rate and poor long-term utilization.[49] A related treatment involving the use of a

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48 Efficacy and Safety, *supra*, at 4; Montague, D.K., et al., *Clinical Guidelines Panel on Erectile Dysfunction: Summary Report on the Treatment of Organic Erectile Dysfunction*, 156 J. Urology 2007-11 (Dec. 1996).

49 Sundaram, C.P., et al., *Long-Term Follow-Up of Patients Receiving Injection Therapy for Erectile Dysfunction*, 49(6) Urology 932-35 (1997); Turner, L.A., et al., *Twelve-Month Comparison of Two Treatments for Erectile Dysfunction: Self-Injection Versus External Vacuum Devices*, 39(2) Urology 139-44 (Feb. 1992).

medicated suppository has been found to have limited efficacy while causing discomfort, pain and burning.[50]

c. The use of a *vacuum device* to draw blood into the corpora cavernosa mechanically coupled with a constrictive ring placed at the base of the penis to keep the blood from flowing out of the penis. Published reports indicate low interest rates among patients and low patient satisfaction rates due to lack of rigidity below the constriction band, awkwardness of using the device in the midst of intimate sexual activity, erections that feel cold, and discomfort.[51]

d. A permanent *prosthetic implant*. Prosthetic implants involve surgical risks, including infection and permanent damage to the penis or scrotum. In addition, the implantation of a prosthetic device makes it certain that a patient will never again be able to have an erection without a prosthetic device because the procedure is invasive and irreversible, requiring the destruction of significant portions of penile tissue in the corpora cavernosa. A third major disadvantage is that there is an unavoidable risk of malfunction of the device and the need for revision surgery. Other

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50 Fulgham, P.F., et al., *Disappointing Initial Results With Transurethral Alprostadil for Erectile Dysfunction in a Urology Practice Setting*, 160 J. Urology 2041-46 (Dec. 1998)

51 Lewis, R.W., and Witherington, R., *External Vacuum Therapy for Erectile Dysfunction: Use and Results*, 15 World J. Urology 78-82 (1997); Turner, L.A., et al., *supra*, at 140-41.

drawbacks include complaints by partners about the sensation of unnatural intercourse, the sensation of cold and complaints about girth and length.[52]

32. The drawbacks of these other treatments for ED are such that, before Viagra® became available, many men afflicted with ED would simply forego treatment and live with ED and its adverse effects on their lives and their partners' lives. For many patients, Viagra® is not only the best treatment for their disorder, but the only treatment they will accept.

33. Unlike all of these other treatments, Viagra® restores the body's natural response to sexual stimulation. Viagra® will not cause an erection in the absence of sexual arousal. A patient taking Viagra® will achieve an erection upon being aroused in precisely the same way that a normal male would achieve an erection.

34. The ideal treatment for ED should be effective, simple to use, noninvasive, non-painful and associated with minimal side-effects.[53] Viagra® was the first, and until late 2003 the only, FDA-approved treatment that satisfies all of these criteria. Moreover, the low rate of discontinuation from treatment during the clinical trials reflects an overall high rate of patient satisfaction with Viagra®, which, in turn, served as the basis for the FDA's determination that Viagra® was an effective oral medication to treat ED.[54]

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52 Lewis, R.W., *Long-Term Results of Penile Prosthetic Implants*, 22(4) Urological Clinics of North America 847-55, at 852-54 (Nov. 1995).

53 Efficacy and Safety, *supra*, at 4.

54 Pfizer Final Study Report: Protocol 148-102, *A Double-Blind, Randomised, Placebo Controlled, Parallel Group, Fixed-Dose, Multicentre Study to Assess the Efficacy and Safety of Sildenafil (UK-92,480) Administered Over Six Months to Male Patients with Erectile Dysfunction* (Jul. 17, 1997); Pfizer Final Study Report: Protocol 148-103, *A Double-Blind Randomised, Placebo Controlled, Parallel Group, Multicentre, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil Administered as Required to Male Patients with Erectile Dysfunction* (Jul. 17, 1997); Pfizer Final Study Report: Protocol 148-363, *A Double-Blind, Randomised, Placebo Controlled, Parallel*

(continued...)

35. Viagra® has become a first treatment option that should be considered for patients afflicted with ED.[55] Unlike the use of a prosthetic implant, it is now unnecessary to subject the patient to a battery of time-consuming and expensive tests to establish that the patient's ED has a biological cause and is permanent. With this innovative medication, it is also unnecessary for the patient to use bothersome and painful injection therapy or cumbersome devices before attempting treatment with Viagra®.

Viagra® Is Markedly Improving The Quality Of The Lives Of Patients And Their Partners; Patient Satisfaction With Viagra® Has Been High

36. To date, I have prescribed Viagra® to more than 3,000 patients whom I have seen in my clinical practice. I have been treating many of these patients for years.

37. Patients experience a high degree of satisfaction with Viagra®. I have observed improvement in the self-esteem and anxiety levels of patients whose ability to engage in sexual activity in response to sexual arousal has been restored with Viagra®. Patients whom I have treated with Viagra® have also reported improvement in their intimate relationships. Whereas patients with ED tend to be uncomfortable about discussing their condition and seeking treatment, patients who have been treated with Viagra® have demonstrated a willingness to speak openly about their experiences, a reflection of their enthusiasm for the treatment. Moreover, Viagra® has encouraged many men with ED to seek treatment in the first place;

Group, Multicentre, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil (UK-92,480) Administered Over Six Months to Male Patients with Erectile Dysfunction (Jun. 30, 1997); Pfizer Final Study Report: Protocol 148-364, *A Double-Blind, Randomised, Placebo-Controlled, Parallel Group, Multi-Centre Study to Assess the Efficacy and Safety of Fixed Doses of Sildenafil Administered for Three Months to Male Patients with Erectile Dysfunction* (Jun. 26, 1997).

55 *See* Consensus Panel, *supra*, at 62, 66 (listing Viagra® first among first-line therapy options).

significantly, by seeking treatment for their ED, these men can be diagnosed, and treated, for other serious health conditions, such as diabetes and hypertension.

38. Viagra® is thus a remarkable advance in the treatment of ED. It is a medication that enables me to treat my patients successfully, comfortably and safely.

VIAGRA Is Appropriately Labeled With Regards To NAION

39. It is important that pharmaceutical labels be accurate and consistent with medical science. In this context, accuracy requires that the label neither understate nor overstate the risk associated with the medication's use. While there are negative consequences with understating a risk, there also are negative consequences with overstating a risk. Patients are harmed if a label inaccurately claims that a risk exists when it does not, because physicians will be deterred from prescribing a potentially beneficial medication that will help the patient.

40. Beginning in 2000, I was aware of case reports that had been published in medical journals reporting that a small number of men taking Viagra (or other PDE5 inhibitors) had developed NAION.[56] These early case reports did not present a sufficient scientific basis to justify discussions with patients about NAION.

41. In July 2005, after additional case reports,[57] the labeling information for Viagra and other oral ED treatments was changed to include information about reports of NAION. Specifically, the label now reads:

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[56] E.g., Egan, R, Pomeranz H., *Sildenafil (Viagra) associated anterior ischemic anterior optic neuropathy*, 118 Arch. Ophthalmol. 291-92 (2000); Pomeranz, HD, et al., *Sildenafil-associated non-arteritic anterior ischemic optic neuropathy*, 109 Ophthalmology 584-587 (2002).

[57] Pomeranz, HD, Bhavsar, AR., *Nonarteritic ischemic optic neuropathy developing soon after use of sildenafil (Viagra): a report of seven new cases*, 25 J. Neuroophthalmol. 9-13 (2005).

> Non-arteritic anterior ischemic optic neuropathy (NAION), a cause of decreased vision including permanent loss of vision, has been reported rarely post-marketing in temporal association with the use of phosphodiesterase type 5 (PDE5) inhibitors, including VIAGRA. Most, but not all, of these patients had underlying anatomic or vascular risk factors for developing NAION, including but not necessarily limited to: low cup to disc ratio ("crowded disc"), age over 50, diabetes, hypertension, coronary artery disease, hyperlipidemia and smoking. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors, to the patient's underlying vascular risk factors or anatomical defects, to a combination of these factors, or to other factors (see PRECAUTIONS/Information for Patients).[58]

42. This label is an accurate reflection of the current medical science. Because vascular disease is a risk factor for both ED and NAION, it is to be expected that some Viagra users will have both ED and NAION. But there is no data showing a statistically significant correlation between the use of PDE 5 inhibitors and NAION.[59]

Dated: December 22, 2008

John J. Mulcahy, M.D.

John J. Mulcahy, M.D.

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58 Viagra Label (August 2008).

59 McGwin, G., Jr., et al., *Non-arteritic anterior ischaemic optic neuropathy and the treatment of erectile dysfunction*, 90 Br. J. Ophthalmol 154-157 (2006); Gorkin, L., et al., *Sildenafil citrate use and the incidence of nonarteritic anterior ischemic optic neuropathy*, 60 Int. J. Clin. Pract. 500-503 (2006); Expert Report of Dr. Stephen Kimmel (Dec. 18, 2008).

Exhibit A

CURRICULUM VITAE

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PERSONAL DATA

Born:	January 7, 1941, New York City
Married:	August 8, 1970 to Rae Anne Snyder, Danville, Illinois
Children:	Lori Anne, born September 28, 1973
	Maureen Lynn, born February 24, 1975
	Michael David, born December 15, 1982
	Mark Douglas, born August 20, 1984

EDUCATION

1954-1958	Xavier High School, New York City
1958-1962	Holy Cross College, Worcester, MA (A.B.-Major in Mathematics)
1962-1966	Georgetown University Medical School, Washington, D.C. (M.D.)

PROFESSIONAL TRAINING

1966-1967	St. Vincent's Hospital, New York City (Medical Intern)
1967-1969	Mayo Clinic, Rochester, MN (Urology Resident)
1969-1972	University of Michigan, Ann Arbor, Michigan Ph.D. in Physiology Thesis: "The Effect of Cardiac Denervation on Body Fluids and Renal Function." Advisor: Richard L. Malvin, Ph.D.
1972-1974	Mayo Clinic (Urology Resident) M.S. in Urology, University of Minnesota Thesis: "The Effects of Intravesical Formalin Instillation on the Destruction and Regeneration of the Canine Bladder Mucosa." Advisor: George M. Farrow, M.D.

PREVIOUS POSITIONS

9/2006-Present – Consultant in Urology-Tucson Veterans Administration Hospital, Tucson, AZ. Clinical Professor of Surgery (Urology) University of Arizona.

1/2006-4/2006 Urology Associates, Ltd., Phoenix, AZ

1978-2006 Professor of Urology
Indiana University Medical Center, Indianapolis, IN

1974-1978 Assistant Professor of Surgery (Urology)
The University of Kentucky, Lexington, Kentucky

HONORS

New York State Regents Science Scholarship, 1958
B.A. Degree - Cum Laude - 1962

Morgan and Avalon Foundation Scholarships - 1963-1966 - Georgetown University Medical School
M.D. Degree - Cum Laude, 1966

Citation - Best Doctors in America, Naifeh, S & G.W. Smith, Woodward/White Aiken, S.C., 1992 - 2007

Cristol Award - 1993
Awarded by the Mayo Clinic Urology Department
For Outstanding contributions to the specialty of Urology

Outstanding Professor in Clinical Sciences
Indiana University School of Medicine
Class of 1996

F. Brantley Scott Award - 2000
Awarded by The Bladder Health Council
Of the American Foundation For Urologic Disease
For Significant Contributions to the Specialty Of Urology

Listed in America's Top Doctors
Castle Connolly Guide 2002-2003-2004-2005-2006-2007

PROFESSIONAL SOCIETIES

American Medical Association (1967)
American College of Surgeons (1977)
Society of University Urologists (1976)
American Urological Association (1978)
Society for Urodynamics & Female Urology (1983)
Societe International d'Urologie (1987)
Sexual Medicine Society (1994)
International Society Sexual Medicine (1992)

FIELDS OF MAJOR SCIENTIFIC INTEREST

Urodynamics - Urinary Incontinence
Neurogenic Vesical Dysfunction
Voiding Disorders
Male Sexual Dysfunction
Genito Urinary Prostheses

LICENSURE

1967 Diplomate, National Board of Medical Examiners Certificate No. 86052
1967 New York State, License No. 98924
1967 Minnesota, License No. 17983
1974 Kentucky, License No. 17564
1978 Indiana, License No. 01028308
2000 Arizona, License No. 28753

CERTIFICATION

Certified, American Board of Urology, 1976
Fellow, American College of Surgeons, 1977

ACADEMIC ADMINISTRATION

Editorial Board _ Urology Times
Editorial Board _ International Journal of Impotence Research
Editorial Reviewer - Journal of Urology
Editorial Reviewer – Urology
Editorial Reviewer – The Journal of Sexual Medicine
Past President- Sexual Medicine Society of North America
Chairman – Coalition for the Advancement of Prosthetic Urology

GRANTS
Principal Investigator:

Renal Perfusion Study: " A Physiologic and Histologic Comparison of In Situ Renal Cooling & In Situ Renal Pulsatile Perfusion." NIH Biomedical Research Support Grant, 1976-78.

Easter Seal Research Foundation Grant: "Pharmacologic Alterations of the Urinary Bladder and Bladder outlet to Achieve Urinary Continence and Incontinence." (N - 7636), 1977
Micropuncture of the Autotransplanted Kidney, NIH Biomedical Research Support Grant, 1978

Evaluation of Ditropan in Myelomeningocele Patients, Marion Laboratory - 1977

Evaluation of Ephedrine SO4 in Myelomeningocele Patients, Eli Lilly Co. 1977

Clinical Trial: 741-742 Artificial Urinary Sphincter, American Medical Systems - 1981

Clinical Trial: Hydroflex Penile Prosthesis, American Medical Systems 1984-1985

Clinical Trial: Bard Penile Prosthesis, C.R. Bard, Inc., Urological Division 1985

Oral single-dose-ranging and safety study with LY163505, Eli Lilly 1985-1990

Clinical Trial: OmniPhase Penile Prosthesis, Dacomed Corporation, 1986-1987

Clinical Trial: DuraPhase Penile Prosthesis, Dacomed Corporation, 1987

Clinical Trial: AMS-873 Artificial Urinary Sphincter, American Medical Systems, 1991-1992

Clinical Trial: Abbott Labs, Terazosin/Hytrin, Treatment for BPH, 1990 - 1991

Clinical Trial: AMS-DP9010 Artificial Urinary Sphincter, American Medical Systems - 1992

Clinical Trial: Smith-Kline Beecham, SKF 105657, Treatment for BPH, 1992

Clinical Trial: Mentor Alpha Excel Inflatable Penile Prosthesis, Mentor Corporation, 1992

Clinical Trial: Amesergide for psychogenic impotence, Eli Lilly, 1992

Clinical Trial: Duloxetine for Urinary Incontinence (phase II), Eli Lilly, 1994

Clinical Trial: Duloxetine for Urinary Incontinence: A Multiple Dose Study of Efficacy & Safety, Eli Lilly 1-24-95 9411-35

Clinical Trial: Ambicor Inflatable Penile Prosthesis follow-up Clinical Study, AMS 2-22-95 9501-07

Clinical Trial: Multi-center Prospective Cohort Study to Evaluate Safety & Effectiveness, AMS 700 Prosthesis American medial Systems, 4-11-95 9503-27

Clinical Trial: Prospective Study Mentor's Alpha I IPP, Mentor 5-2-96 9604-06

Clinical Trial: Prospective Study to Evaluate Safety & Effectiveness AMS 800 Urinary Sphincter, American Medical Systems, 2-11-97 9701-02

Clinical Trial: Evaluation of the Safety and efficacy of MUSE (Alprostadil) Plus the Actis Venous Flow Controller in Men with Erectile Dysfunction, Vivus 6-13-97 9507-13

Clinical Trial: A Randomized, Double-Blind, Placebo-Controlled, Two years parallel Group Study of the Efficacy & Safety of GI198745 0.5mg in the Treatment and Prevention of BPH, Glaxo Wellcome 7-1-97 9706-01

Clinical Trial: A Multi-Center Retrospective Cohort study to evaluate the Safety & Effectiveness of the American Medical Systems (AMS) Sphincter 800 TM Urinary Prosthesis, American Medical System, 8-28-96 9608-02

Clinical Trial: A Phase III Efficacy & Safety Study of Four Fixed Doses of Spontain Tablets (Apomorphine) vs. Placebo in Treatment of Male Erectile Dysfunction, TAP 9-5-97 9708-13

Clinical Trial: Evaluations of Safety & Efficacy of MUSE for Enhancement of Penile Girth & Length in Men having received a penile prosthesis, VIVUS 10-2-97 9709-33

Clinical Trial: A Phase IV, Multi center, open label, Flexible dose Escalation study to evaluate the correlation between event log parameters, self-esteem/ overall relationship, and efficacy of Viagra (sildenafil citrate) in men with Erectile Dysfunction. Pfizer 01-10-98 0205-34
Clinical Trial: Predictors of drug utilization and outcomes in men with erectile dysfunction receiving Viagra. The Kinsey Institute 03-16-99; 98-2720

Clinical Trial: Clinical Investigation of the Safety and Performance of The Timm Medical Technologies Artificial Urinary Sphincter (Timm- AUS) Timm Medical 04-20-99; 9904-35

Clinical Trial: A multi center randomized blinded, controlled trial to investigate the safety and efficacy of the urethral bulking agent, macroplastique for the treatment of female stress urinary incontinence. Urolplasty, Inc. 11-3-99; 9910-16

Clinical Trial: Use of an externally applied vacuum erection device to enhance erectile ability in patients exhibiting a partial response to Viagra. Timm Medical 02-21-00; 0001-47

Clinical Trial: A randomized, Double – Blind placebo- controlled, dose-finding study of Topiglan (Topical gel formulation of Alprostadil and SEPA) for the treatment of male erectile dysfunction in an at-home setting. Macrochem 07-13-00; 0007-41

Clinical Trial: A randomized double blind placebo controlled study of the efficacy and safety of IC351 (LY 450T90) administered "on demand" to patients with erectile dysfunction. Lilly-ICOS 04-11-01; 0103-08

Clinical Trial: A randomized, double-blind, placebo-controlled study of the efficacy and safety of IC 351 (LY 450F10) administered "on demand" to patients with erectile dysfunction following bilateral nerve-sparing radical retropubic prostatectomy. Lilly-ICOS 01-15-02; 0112-14

PUBLICATIONS

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Mulcahy, J.J., Kelalis, P.P., Stickler, G.B. and Burke, E.C.: Familial vesicoureteral reflux. J. Urol.,

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Greene, L.F., Mulcahy, J.J., Warren, M.M. and Dockerty, M.B.: Primary transitional cell carcinomas of the prostate. J. Urol., 110: 235-237, 1973

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Mulcahy, J.J., Brandenburg, R.O., Pluth, J.R. and Greene, L.F. Transurethral prostatic resection in patients with prosthetic cardiac valves, J. Urol., 113: 642-649, 1975

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Foster, R.S., Rink, R.C., and Mulcahy, J.J.: Focal salmonella enteritidis infection of urinary tracts, Urology 29: 646-647, 1987

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Mulcahy, J.J.: Penile prostheses and dermal grafts in Peyronie's Disease, Audio Digest Foundation, V.12, No.7, 1989

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Mulcahy, J.J.: Managing impotence, Advances in Urology, Audio cassette, January, No. 1, 1990

Mulcahy, J.J.: The management of infected penile implants, World J. Urol., V.8, 111-113, No. 2, 1990

Mulcahy, J.J.: Neurologic Assessment of Impotence, Audio Digest Foundation, V.13, No. 6, 1990

Mulcahy, J.J.: Urinary Incontinence - Awareness and Education Needed, AUA Today, Vol. 3, No. 89, 1990

Mulcahy, J.J.: Restoring continence with an artificial urinary sphincter, Contemporary Urology, October, 22-28, 1990

Mulcahy, J.J.: Overview: The Management of Peyronie's Disease, Current Operative Urology, Vol. 2, 1991

Mulcahy, J.J., The management of complications of penile prostheses and the artificial urinary sphincter, Practical Cases in Urology, Series 13, Course #2, 1990

Foster, R.S., Mulcahy, J.J., Callahagn, J.T., Crabtree, R., and Brashear, D.: The role of serum prolactin determination in evaluation of the impotent patient, Urology, V.36, 499-501, 1990

Mulcahy, J.J.: For male sexual dysfunction, more to offer patients, Contemporary Urology, Vol. 13.

No. 1, 67-68, 1991

Mulcahy, J.J.: Take the message to the public (Editorial), Contemporary Urology, February 1991, Vol. 3, No.2, p.9

Mulcahy, J.J., Montague, D.K., Goldstein, I.: Impotence therapy fulfills a promise, Contemporary Urology, February 1991, Vol 3, No.2, p. 51-57

Mulcahy, J.J., Update on Penile Prostheses, Current Opinion in Urology, 1, 152-155, 1991

Mulcahy, J.J., Management of complications of penile implants, Problems in Urology 5, 608-627, 1991

Mulcahy, J.J., Guarded optimism is watchword for future of penile prostheses, Urol. Times, Vol. 19, No. 12, p. 10, 1991

Mulcahy, J.J., An evaluation of the types of penile implants, World Book of Impotence, Chapter 16, p. 237-244, 1992

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Mulcahy, J.J., Implantation of Hydraulic Penile Prostheses. Atlas of Urol. Clin. N.A. 1: 71-92, 1993

Mulcahy, J.J., Lewis, R.W., Lue T.F., Melman, A., and Padma-Nathan, H. In Pursuit of the best canidates and procedures for penile revascularization, Contemporary Urology 5: No. 5, 27-43, 1993

Mulcahy, J.J. Taking the history: Questions to ask the patient with erectile dysfunction. Contemporary Urology 5: No. 5, 64-70, 1993

Mulcahy, J.J., Cerniglia, F. R., Jr., Cummings, J.M., Holcomb, F.L., Licker, K.I., Mardis, H.K., and Weiner, S.M.Urologists Speak Their Mind About the Speciality. Contemporary Urology 5: No. 9., 29-42, 1993

Mulcahy, J.J., Mechanical Penile Prostheses. Problems in Urology 7: No. 3, 311-316, 1993

Mulcahy, J.J., Pevention and Correction of Penile Implant Problems. AUA Update Series Vol XIII Lession 27, 1994.

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Exhibit B

Testimony by John J. Mulcahy, M.D.

At Trial:

7/2/04 - Eppinette vs Dr. Dunshee. Tucson, AZ
8/9/04 - Chleapas vs. Dr. Zinman. Boston, MA
8/14/04 - Thomas vs Dr. Chiu. Bronx, NY
3/1/07 - Hale vs Dr. Ransome. Valparaiso, IN

At Deposition:

1/6/04 - Re. Mr L. Sumpter. Anderson, IN
4/10/04 - Eppinette vs. Dr Dunshee. Tucson, AZ
4/10/04 - Clark vs. Dr. Newman. Tucson, AZ
8/2/04 - Re. D. Harris. Indianapolis, IN
11/17/04 - Lewis vs. Dr Borrego, et al. Sunrise, FL
1/28/05 - Hove vs. Dr. Goldberg. Dallas, TX
4/18/05 - Ricci vs. Dr. Stein. Plantation, FL
12/2/05 - McCalup vs. Dr. Patel. Tampa, FL
2/13/06 - Green vs. Dr. Patel. Tampa, FL
6/15/06 – Jett vs. Dr. Cockrell. E. St Louis, IL